

REMARKS

Applicants thank the Examiner for the courtesy extended to Applicants' attorney during the discussion held April 2, 2003, in the above-identified application. During the discussion, Applicants' attorney explained the presently-claimed invention and why it is patentable over the applied prior art, and discussed other issues raised in the Office action. The discussion is summarized and expanded upon below.

The present invention is drawn to novel compounds, having a particular utility for treating or preventing Tachykinin-mediated diseases.

The rejections of Claims 11 and 13-16 under 35 U.S.C. § 103(a) as unpatentable over WO 98/57954 (Miyake et al), is respectfully traversed. In the compounds of Miyake et al, R² is aryl or indolyl, each of which may have a substituent. However, Miyake et al discloses no compounds wherein R² is phenyl substituted with two substituents, wherein at least one of the substituents is hydroxy.

In the present Office Action, the Examiner finds that the presently-claimed compounds differ from Miyake et al by requiring a hydroxyl group in R², while Miyake et al has a corresponding methyl group, and holds that replacing the methyl with hydroxyl would have been obvious. The Examiner particularly relies on compound (3) of Example 80 (Example 80-(3)) therein. In reply, the newly-submitted second Matsuo Declaration compares Example 5-(1) shown in the Declaration under 37 C.F.R. §1.132 of Masahiko Matsuo filed January 15, 2003 (first Matsuo Declaration), together with two other compounds within the terms of the present invention with differing R¹ groups but also having a hydroxyl-substituted phenyl for R², to said Example 80-(3) of Miyake et al. The data show that the compounds of the present invention are 2.4-3.3 times stronger than Example 80-(3) of Miyake et al regarding capability of h-NK₁ receptor binding. Applicants respectfully submit

that they have thus demonstrated the significance of such hydroxyl-substitution on the phenyl for R².

For all the above reasons, it is respectfully requested that the rejections over Miyake et al be withdrawn.

The rejection of Claims 11-18 under 35 U.S.C. § 103(a) as unpatentable over WO 97/22597 (Matsuo et al), is respectfully traversed. Like Miyake et al, above, Matsuo et al does not disclose any compounds wherein R² is phenyl substituted with two substituents, wherein at least one of the substituents is hydroxy. The Examiner appears to rely on the compounds of Examples 81 and 87 of Matsuo et al as the closest prior art, which compounds contain a dimethyl-substituted benzyl ring, while the present invention is inclusive of a methyl-, hydroxy- substituted benzyl ring. In reply, the first Matsuo Declaration shows the results of a comparison of the capability of h-NK1 receptor binding between the compound of present Claim 18, and the compound of Example 81 of Matsuo et al. The binding capability of the representative compound of the present invention is more than 5 times (5.6 times) as strong as that of the compound of said Example 81. Clearly, one skilled in the art could not have predicted this significant difference from the disclosure of Matsuo et al.

In the Office Action, the Examiner first finds that the above-asserted 5-fold activity difference has not been asserted to be unexpected and of both statistical and practical significance, citing *Ex parte Gelles*, 22 USPQ2d 1318 (Bd. Pat. App. & Inter. 1992).

In reply, since the cited prior art does not recognize any significant difference in activity among the compounds embraced therein, it would seem superfluous to have to assert that a 5-fold activity difference is unexpected. Of course it is. Nor can there possibly be any question that the difference has practical significance. Regarding statistical significance, the CCPA has indicated that where the patent applicant has not asserted statistical validity, evidence may not be dismissed simply because statistical validity has not been shown. *In re*

Kollman, 595 F.2d 48, 56 n.8, 201 USPQ 193, 199 n.8 (CCPA 1979) (**copy enclosed**) ("The board also questioned the statistical significance of the proof. Admittedly the number of plants used in the tests is not disclosed. Nevertheless, *we see no reason to question the data on this basis without some indication either from the data or from the prior art that these types of tests give unreliable results.*" (Emphasis added.))

In the Office Action, the Examiner further finds that the compound of the present invention tested in the first Matsuo Declaration (Example 5-(1)) is not the embodiment of the claimed invention closest to said Example 81 of Matsuo et al. In reply, the newly-submitted third Matsuo Declaration compares the above-discussed compounds of the present invention tested in the second Matsuo Declaration, to Example 53-(1) of Matsuo et al. Example 53-(1) of Matsuo et al has the same R² group as above-discussed Example 80-(3) of Miyake et al but a different R⁴ group. The data show that the compounds of the present invention are 7-9 times stronger than Example 53-(1) of Matsuo et al regarding capability of h-NK₁ receptor binding.

The Examiner also finds that the testing as described in the specification was conducted to determine 80% inhibition but the first Matsuo Declaration tested 50% inhibition. In reply, under the heading "[II] Test Result" at page 26 of the specification, it is described that "[a]ll of the following Test Compounds showed more than 80% inhibition rate of ¹²⁵I-BH-Substance P binding to h-NK₁ receptors at the dose of 1 mg/kg." The 80% inhibition rate does not mean IC₈₀, but rather that these Test Compounds showed more than 80% inhibition at a single dose of 1 mg/kg of each compound. On the other hand, IC₅₀ is calculated from plural figures measured at several doses including a dose of 1 mg/kg. Thus, there is no inconsistency.

For all the above reasons, it is respectfully requested that the rejections over Matsuo et al be withdrawn.

The rejections of Claims 11-18 under the judicially-created doctrine of obviousness-type double patenting over the claims of commonly-assigned U.S. 6,087,357, or of copending Application No. 09/446,145, are respectfully traversed. Applicants respectfully submit that the present claims are not rendered obvious by any of the claimed subject matter of the above commonly-assigned patent and copending application, particularly in view of the data provided with the newly-submitted second and third Matsuo Declarations, along with the first Matsuo Declaration of record, and all the other evidence in the application.

For all the above reasons, it is respectfully requested that these rejections be withdrawn.

Regarding the first paragraph at page 5 of the Office Action, this was already responded to at page 7 of the amendment filed December 20, 2002, to wit, regarding the above-identified commonly-assigned patent and copending application, the subject matter claimed in each, and the claimed invention, were, at the time the claimed invention was made, commonly owned.

The rejection of Claim 16 under 35 U.S.C. § 112, first paragraph, is respectfully traversed. Indeed, the rejection is now moot in view of the above-discussed amendment. Accordingly, it is respectfully requested that it be withdrawn.

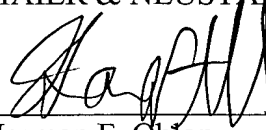
Submitted herewith is a copy of an EPO communication, dated December 3, 2002, that discloses prior art already of record.

Application No. 09/857,869
Reply to Final Office Action of March 13, 2003

All of the presently-pending claims in this application are now believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Norman F. Oblon
Attorney of Record
Registration No. 24,618

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 08/03)
NFO/HAP/cja

Harris A. Pitlick
Registration No. 38,779

In re Kollman and Irwin, 201 USPQ 193 (CCPA 1979)

In re Kollman and Irwin

**(CCPA)
201 USPQ 193**

Decided Mar. 15, 1979

No. 78-624

U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Patentability -- Anticipation -- In general (§ 51.201)

Section 102 rejection is reversed where it is apparent that there is no suggestion of required ratio of composition's components, even disregarding fact that prior art fails to highlight claimed composition among many dozens disclosed.

2. Patentability -- Evidence of -- In general (§ 51.451)

Patentability -- Invention -- In general (§ 51.501)

Examples that show presence of unexpected result in one species do not provide adequate basis for concluding that great number of compositions of generic claim would behave in same way.

3. Patentability -- Aggregation or combination -- New or better result (§ 51.157)

Patentability -- Invention -- In general (§ 51.501)

Synergism, in and of itself, is not conclusive of unobviousness in that synergism might be

expected; nonobviousness is correct statutory standard.

4. Patentability -- Aggregation or combination -- New or better result (§ 51.157)

Patentability -- Composition of matter (§ 51.30)

Patentability -- Invention -- Specific cases -- Chemical (§ 51.5093)

Conclusion that unobvious result is demonstrated if effectiveness of claimed mixture, for example, 1 pound of A and 1 pound of B per acre, is greater than total of two tests, for example, 2 pounds of A per acre and 2 pounds of B per acre, may well be correct, but requirement that claimed mixture be compared to equal weight of its constituents is not found in *In re Lemin*, 161 USPQ 288.

5. Patentability -- Composition of matter (§ 51.30)

Patentability -- Evidence of -- State of art (§ 51.467)

Patentability -- Invention -- In general (§ 51.501)

Although industrial standards are not necessarily determinative of what constitutes unobvious result, they should go long way in evincing what one having ordinary skill in art looks at in making choice between compositions.

6. Patentability -- Evidence of -- In general (§ 51.451)

There is no reason to question data on basis of inadequate statistical significance of proof, even though number of items tested is not disclosed, without some indication either from data or from prior art that these types of tests give unreliable results.

7. Patentability -- Evidence of -- In general (§ 51.451)

Patentability -- Invention -- In general (§ 51.501)

Unobviousness of broader claimed range can, in certain instances, be proved by narrower range of data; often, one having ordinary skill in art may be able to ascertain trend in exemplified data that would allow him to reasonably extend its probative value; proof, thus considered, might

then be sufficient to rebut Patent and Trademark Office holding of prima facie obviousness.

Particular patents -- Herbicidal Composition

Kollman and Irwin, Synergistic Herbicidal Composition, rejection of claims 1, 3-6, and 9-15 affirmed; rejection of claims 7 and 8 reversed.

Case History and Disposition:

Page 193

Appeal from Patent and Trademark Office Board of Appeals.

Application for patent of Gerald E. Kollman and Elwood N. Irwin, Serial No. 547,292, filed Feb. 2, 1975. From decision rejecting claims 1 and 3-15, applicants appeal. Modified.

Attorneys:

Terence P. Strobaugh, Lansdale, Pa., for appellants.

Joseph F. Nakamura (Gerald H. Bjorge, of counsel) for Commissioner of Patents and Trademarks.

Judge:

Before Markey, Chief Judge, and Rich, Baldwin, Lane, and Miller, Associate Judges.

Opinion Text

Opinion By:

Baldwin, Judge.

This appeal is from the decision of the Patent and Trademark Office (PTO) Board of Appeals (board) affirming the rejection of

Page 194

claims 1 and 3-15 ¹ in appellants' application serial No. 547,292, filed February 5, 1975, for "Synergistic Herbicidal Composition."

The board affirmed the examiner's rejection of all claims under 35 USC 103 as unpatentable

"over the teachings of Bayer et al., Poignant et al., Inoue et al., and Tischler." The board also entered new rejections, pursuant to its authority under 37 CFR 1.196(b), ² of the claims under 35 USC 103 or 102 over Bayer et al. We reverse the decisions of the board concerning the §102 rejection of all claims and the §103 rejection of claims 7 and 8, and affirm its decision regarding the §103 rejection of the remaining claims.

The Invention

Appellants have found that certain herbicidal compositions containing 2,3,6-trichlorophenylacetic acid (hereinafter FENAC) and certain diphenyl ethers exhibit desirable activity when used against nutsedge (or Cyperus) weeds.

The following claims are illustrative of the invention:

1. A synergistic herbicidal composition comprising (A) 2,3,6-trichlorophenylacetic acid, or an agronomically acceptable salt, ester, or amide thereof, and (B) a diphenyl ether herbicide, wherein the weight ratio of (A) to (B) is about 1:10 to about 20:1.

3. The composition of claim 2 [sic] wherein the weight ratio of (A) to (B) is about 1:1 to about 4:1.

5. The composition of claim 4 wherein the diphenyl ether has the formula
Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

wherein R₁ is a hydrogen atom, a (C₁-C₄) alkoxy group, a carboxy group, a carb (C-C₄)

alkoxy group, or a carb (C₁-C₄)alkoxy (C-C₄)alkoxy group,

R₂ is a chlorine atom or a nitro group,

R₃ is a chlorine atom or a trifluoromethyl group, and

R₄ is a hydrogen atom, a chlorine atom, or a fluorine atom.

6. The composition of claim 3 wherein the diphenyl ether is 2,4-dichlorophenyl 4-nitrophenyl ether.

7. The composition of claim 3 wherein the diphenyl ether is 2-chloro-4-trifluoromethylphenyl -3- ethoxy -4- nitrophenyl ether.

8. The composition of claim 3 wherein the diphenyl ether is 2-chloro-4-trifluoromethylphenyl 3-carbomethoxy-4-nitrophenyl ether.

10. A method of controlling weeds which comprises applying to the weeds a composition according to claim 1 in a herbicidally effective amount.

Issue

The dispositive issues in this case pertain to whether the examples in the specification are demonstrative of unobvious results and, further, whether those unobvious results are sufficient to overcome the §103 rejections.

The Prior Art

The following references were applied against the claims:

Bayer et al. Patent No. 3,798,276 issued on March 19, 1974.

Poignant et al. Patent No. 3,484,230 issued on December 16, 1979.

Inoue et al. Patent No. 3,401,031 issued on September 10, 1968.

Tischler Patent No. 2,977,212 issued on March 28, 1961.

Page 195

Bayer et al. (hereinafter Bayer) discloses diphenyl ethers having the general formula:
Graphic material consisting of a chemical formula or diagram set at this point is not available.
See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

wherein

X is a hydrogen atom, a halogen atom, a trihalomethyl group, an alkyl group, or a cyano group,

Y is a hydrogen atom, a halogen atom or a trihalomethyl group, and

Z is an alkoxy group, an alkoxyalkoxy group, a hydroxyalkoxy group, an alkyl group, a halogen atom, an alkylamino group, a dialkylamino group, an alkylthio group, a carboxy group, a carbalkoxy group, a carboxyalkyl group, a carbalkoxyalkoxy group, a carboxyalkyl group [sic], a carbalkoxyalkyl group, a dialkylureido group, an alkanoylamino group, or a carbalkoxyamino group,

as a herbicide effective against a number of weeds including the monocot nutsedge (Cyperus). Bayer also suggests that these diphenyl ethers be mixed with other herbicides including, inter alia, FENAC.

The other references are cumulative in technical content to Bayer and need not be discussed

in detail.

It is noted, however, that Poignant et al. (hereinafter Poignant) mentions a test which is said to show up the presence of "synergism" in combination herbicides:

This test [was] * * * disclosed by Colby in the magazine "Weeds," January 1967, pp. 20-22.

Let us resume the principle of said method:

Assuming X_1 is the percentage of plants not killed by herbicide A at the dose p, and Y is the percentage of plants not killed by herbicide B at the dose q, the "expected" percentage, E, of plants not killed by the mixture (A+B) at the dose (p+q) is:
Graphic material consisting of a complex mathematical formula set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

Then, it is only necessary to compare E_1 with the actual percentage, E, of plants not killed by (A+B) at the dose (p+q) to know the character of the combined action of the two herbicides.

If E_1 is higher than E, there is synergy. In the opposite case, there is antagonism.

Background

Appellants' brief before the board presented the following argument:

Initially, applicants concede that each of the components of the claimed compositions is a known herbicide. Thus, in order to establish the patentability of their compositions, applicants must show that the combination of those known herbicides produces a composition having unexpected properties.

In the specification of the present application, applicants have presented three tables of data * * * showing the effectiveness of compositions of the invention against yellow and purple nutsedge at various rates and ratios, together with comparative data showing the activity of each of the individual components of the composition used alone at the same rate as each is present in the compositions. This data demonstrates that the herbicidal activity of the claimed compositions against nutsedge is greater than the expected additive activity of each of the components used alone. For example, in Table I, ³ diphenyl ether I used alone at

Page 196

4 lb/A controlled 50% of yellow nutsedge, while fenac used alone at 2 lb/A controlled a combination of 4 lb/A of diphenyl ether I with 2 lb/A of fenac controlled 99% of yellow nutsedge, rather than 50% control which would be expected from merely additive

activity. Similarly, in a typical example of Table II ⁴ diphenyl ether III used alone at 1/2 lb/A controlled 60% of yellow nutsedge, while fenac used alone at 1 lb/A controlled 10% of yellow nutsedge. However, the *combination* of 1/2 lb/A of diphenyl ether III and 1 lb/A of fenace controlled 85% of yellow nutsedge, rather than the 70% control which would be expected if the activity of the individual components was just additive. Numerous additional specific examples are set forth in the table which also show this unexpectedly good activity for compositions in which the ratio of diphenyl ether to fenac varies from 1:16 to 16:1. Thus, while one skilled in the art would expect that the two individual components of the claimed compositions would act upon the plants independently and give at best an additive herbicidal effect, the data presented in the tables reflects a coaction between the two components when used together to produce significantly greater than additive herbicidal activity.

The examiner responded to these arguments in the Answer:

Appellants point to various examples of data presented in the specification as establishing synergism at other than the 1:1 ratio. This position is not well taken. This data satisfies but part of the criteria set to determine if synergism exists. For instance appellants point to the test in table I employing 4 lbs. of the ether in combination with 2 lbs. of fenac. However there is no testing of the ether at 6 lbs. nor the fenac at 6 lbs., i.e. no testing of the individual components at the total amount of the combination employed.

The legally accepted definition of synergism as meaning "the combined action of two or more agents * * * that is greater than the sum of the action of one of the agents used alone" is cited in *In re Luvisi et al*, 144 USPQ 646. *In re Lemin et al*, 161 USPQ 288 points out the necessity of presenting data for each component singly at the total rate applied in combination in addition to the fact that each component must be tested individually at the rate at which it appears in combination.

Thus, other than in the case of the active ingredients employed in a 1 to 1 ratio the data is not seen to satisfy the requirements necessary to establish synergism.

The board agreed with the examiner that the exemplified data were insufficient to overcome the §103 rejection, but did so for substantially different reasons:

As we have indicated hereinbefore, we have found the comparative data in Appellants' specification insufficient to negate the prima facie case of obviousness presented by the Examiner's application of the prior art. We do not agree with the Examiner's statement that the only data supporting synergism occurs at a 1:1 ratio of the active ingredients. Nor do we agree that it is always necessary to show testing of individual components at a *total* amount corresponding to the total of combination employed. We find the data nonpersuasive for a variety of reasons. First, there is no indication that a statistically significant number of test plants or replicates was employed. The test procedure described in the specification at pages 9-10 does not even provide any actual number of plants per flat or any number of flats. Nor do we find data, in a

statistically significant number or otherwise, supporting the allegations of synergism over the entire range claimed by Appellants of 1:10 to 20:1 of Fenac: diphenyl ether. In Table I an unexpected result is indicated at ratios of 1 Fenac to 2, 4 and 8 of ether I. Synergism may also be indicated at proportions 1:1 using ether

Page 197

VI and ether VII. Similarly, there is a showing at 1:2 and 1:4 in Table III, ⁵ again using ether I.

The board entered a new rejection of the claims under §102 or §103 as unpatentable over Bayer and added:

Turning to our new rejection under 35 USC 102/103 in view of Bayer et al., even were all the data in the specification statistically significant, persuasive of synergism, and free of all the criticisms we have made, still the showing would not be relevant to refute the strong prima facie case of obviousness presented by this patent of Appellants' assignee. None of the showings of record compares for herbicidal effectiveness the Bayer et al. diphenyl ethers in combination with Fenac * * * its adjacent homolog (the corresponding benzoic acid compound * * *) or any other of the listed carboxylic acids and derivatives, to demonstrate that Appellants' specific combinations as claimed, within the specific but very broad weight ratios claimed, have such synergistic effects as to provide more than the "additional advantages and effectiveness" expected by the patentees.

Appellants argued in a request for reconsideration that the §102 rejection was improper since:

[T]he Bayer et al reference fails to provide any suggestion that such [disclosed] "additional advantages and effectiveness" would be other than the expected additive effect against individual weeds of combining two known herbicides or the expected complementary activity of two known herbicides which have different spectra of activity. The Bayer et al patent further fails to give any suggestion that combinations of diphenyl ethers and 2, 3, 6-trichlorobenzoic acid would be *expected* to be synergistic. To infer such suggestions from the Bayer et al disclosure would turn the world upside down by assuming that synergistic or greater than additive activity would *normally* be expected from a combination of conventional herbicides by those skilled in the art. Since applicants [sic] compositions represent a selection of a specific known herbicide from among many known herbicides, and a selection of specific ratios for this known herbicide and the diphenyl ether, and in claims 4 to 8 even the selection of specific subgenera and species of diphenyl ether herbicides. [sic] [?] They define a class of herbicidal compositions which is not taught by the Bayer et al patent, and are thus not anticipated under 35 U.S.C. 102.

With regard to the §103 rejection, appellants argued that the board recognized that the data demonstrated "that certain compositions of diphenyl ethers and FENAC do possess unexpected

activity or synergism." Appellants then argued that the showing of "unexpected results"

for proportions of ether I at 1:2 and 1:4 with fenac * * * fully supports the patentability of claim 6, which is directed solely to combinations of ether I in proportions of fenac of 1:1 to 1:4. Thus, it is believed that the decision of the Board supports the *reversal* of the first rejection of claim 6.

The data presented in Tables I and II is at least as conclusive a showing of unexpected results or synergism for ether II as for ether I. For example, in Table I, the data shows fenac to be essentially inactive against yellow nutsedge at one pound/acre, and ether II to provide 50% or less control of this weed at rates of 1/8, 1/4, and 1/2 pound/acre. However, combinations of fenac, at one pound/acre with ether II at 1/8, 1/4, and 1/2 pound/acre all provide control of yellow nutsedge significantly in excess of 70%. The data in Table II involving ether II provides even more compelling evidence of unexpected activity. Moreover, although no specific data is provided for 1:1 ratio of ether II and fenac in Tables I or II, one skilled in the art would certainly extrapolate the data presented in these tables and conclude that similar unexpected control of nutsedge would be obtained, for example, with a composition of one pound/acre of ether II and one pound/acre of fenac. Thus, it is believed that the data when read in the light of the Board's decision supports the *reversal* of the final rejection of claim 7.

The Board has also questioned whether the data is "statistically significant." However, no guidance has been provided by the Board to allow applicants to deter

Page 198

mine whether the herbicidal data set forth in the application would meet any standards of significance which the Board might apply. The Board nevertheless has apparently been provided with sufficient data to allow them to state unequivocally that certain of the test results are unexpected. * * * Regardless of the question of statistical significance, it would seem that art-recognized tests carried out by trained scientists and incorporated into a patent application should be believed by the Patent and Trademark Office in the absence, as in the present case, of any evidence to *doubt* the correctness of the test results or their statistical significance. [Emphasis in original.]

Opinion

Section 102 Issue

The board indicates that it considers our decision in *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978) as mandating a finding that the claims are anticipated by Bayer. We do not agree.

In *Schaumann*, appellants claimed a specific compound within a prior art (Hildebrandt's) genus. There it was observed:

In response to appellants' primary argument that the general formula of Hildebrandt's specification cannot constitute an anticipation of every one of the one hundred and five or more compounds encompassed thereby, the examiner noted that the method disclosed by Hildebrandt for producing b-(meta-hydroxyphenyl)-isopropylamines would result only in the production of secondary amines, thus limiting to fourteen the number of possible compounds taught by the reference. That number is further reduced to seven, said the examiner, if one considers the preference for lower alkyl secondary amines expressed in claim 1 of the reference.

Id. at 314, 197 USPQ at 7.

We agreed, noting:

When we consider also that claim 1 of the Hildebrandt patent, read in conjunction with the signification given the expression "alkyl radical" in the specification, embraces a very limited number of compounds closely related to one another in structure, we are led inevitably to the conclusion that the reference provides a description of those compounds just as surely as if they were identified in the reference by name. Since one of the compounds thus described is HEP [the claimed species], we agree with the examiner and the majority of the board that appellants' right to a patent thereon is barred under 35 USC 102(b).

Id. at 316, 197 USPQ at 9.

[1]In the case at hand, even disregarding the fact that Bayer fails to highlight the claimed composition among the many dozens disclosed, it is apparent there is no suggestion of the required FENAC/diphenyl ether ratio. Accordingly, we reverse the §102 rejection.

Section 103 Issue

Appellants note in their brief that they had conceded that the individual herbicides embraced by appellants' combination were known * * *. Bayer et al. discloses that its original species [the diphenyl ethers] could be combined with many known herbicides including the compound 2,3,6-trichlorophenyl-acetic acid which is the compound "Fenac."

Thus, we need only determine whether the examples are of sufficient weight to overcome the teachings of Bayer. Appellants' assertion that those examples overcome the PTO's holding of obviousness has at least some merit.

[2]As a starting point, we recognize that even if each of the examples showed the presence of an unexpected result, those examples would not provide an adequate basis for concluding that the great numbers of compositions recited in generic claims 1, 3-5 and 9-15 would behave in the same way. See *In re Greenfield*, 571 F.2d 1185, 197 USPQ 227 (CCPA 1978), and cases cited therein. Hence, we affirm the holding of the board with regard to these claims.

However, the data said to support the patentability of species claims 6-8 require further analysis.

[3]One issue that need be considered is the very presence of unobvious results in the data. ⁶

Page 199

The record presents three different methods of assessing data for the existence of unobvious results when combination herbicides are claimed.

[4]The first test, embraced by the examiner and discarded by the board, is based on our decision in *In re Lemin*, 56 CCPA 1050, 408 F.2d 1045, 161 USPQ 288 (1969). Our opinion is said to require testing that compares the effectiveness of a claimed mixture of, e.g., 1 pound of A and 1 pound of B per acre, with that of 2 pounds of A per acre as well as 2 pounds of B per acre. It is said that if the effectiveness of the claimed mixture is greater than the total of the two single tests, then an unobvious result is demonstrated. The conclusion may well be correct, but a requirement that the claimed mixture be compared to an equal weight of its constituents is not to be found in *Lemin*.

Another manner of evaluating these data is disclosed by Poignant. This method compares the actual effectiveness of each of the components in the mixture -- at the amounts present in the mixture -- with the effectiveness of the mixture itself. For instance, if one pound per acre of herbicide A kills 50% of the plants and half a pound of herbicide B kills 50% of the plants, then, according to Poignant, if the effectiveness of the mixture is more than 75%, an unobvious result is shown. This test rests on the theory that if A kills 50% then the best B can do is kill 50% of the *remaining* plants for an expected total of 75%.

The method applied by appellants and the board is similar to that utilized by Poignant, except that the effectiveness rates of the single herbicides are merely added. For the hypothetical situation outlined above, the expected effectiveness for the mixture would be 100%.

[5]We evaluate the examples with the latter method simply because of the ostensible agreement between the board and appellants that it is appropriate. ⁷

In any event, each of the entries in Tables I, II and III for compositions containing ethers I, II and III shows unobvious results under this test since the efficacy of the mixtures is, in each case, higher than the sum of the effectiveness of the constituent herbicides.

[6]The next point at issue concerns the scope of proof offered in support of these claims. ⁸

Claims 6, 7 and 8 all require a FENAC/diphenyl ether ratio ranging between 1:1 and 4:1. Tables I, II and III (footnotes 3, 4 and 5, *supra*) provide data for a range of 1:1 to 2:1 for the composition of claim 6 (containing ether I) and a range of 2:1 to 4:1 for the compositions of claims 7 and 8 (containing ethers II and III respectively). The solicitor argues that the lack of data

for the remainder of the claimed ranges mandates an affirmance of the board's decision.

[7] We feel that the unobviousness of a broader claimed range can, in certain instances, be proven by a narrower range of data. Often, one having ordinary skill in the art may be able to ascertain a trend in the exemplified data which would allow him to reasonably extend the probative value thereof. The proof, thus considered, might then be sufficient to rebut a PTO holding of prima facie obviousness.

The data pertinent to claims 7 and 8 appear to support such an extension, those to claim 6 do not appear to do so.

First, with regard to claims 7 and 8, consider in Tables I and II in the column marked 2 lb/acre of FENAC, the three entries for each of ethers II and III. These entries -- going down the table -- are equivalent to 16:1, 8:1 and 4:1 FENAC/diphenyl ether. The effectiveness *increases* as it approaches the contested region of the claimed range and yet still far outstrips the additive total of "expected" effectiveness. A similar conclusion may be drawn from the entries in the column drawn to 1 lb/acre of FENAC corresponding to ratios of 8:1, 4:1 and 2:1.

On the other hand, the data in Tables I and III corresponding to claim 6 (ether I) cover only a third of the range of claim 6 (1:1 to 2:1), and the effectiveness appears to decrease to the "expected" level as the untested region of that claimed range is approached. For instance, the entries at 1 pound/acre of ether I at both 1 and 2

Page 200

pounds/acre of FENAC, (corresponding to 1:1 and 2:1 ratios, respectively) show the effectiveness to be only 30% and to approach the expected levels of 0% to 10%. Accordingly, the data do not support the breadth of claim 6.

In sum, we *affirm* the board's decision with regard to claims 1, 3-6 and 9-15, and *reverse* as to claims 7 and 8.

Modified.

Footnotes

Footnote 1. We note that claims 3-9 are dependent upon claim 2, a claim cancelled during the prosecution of this application. For the purposes of this appeal, we treat claims 3-9 as containing the limitations of claims 1 and 2.

Footnote 2. 37 CFR 1.196(b) provides, in pertinent part, that:

(b) Should the Board of Appeals have knowledge of any grounds not involved in the appeal for rejecting any appealed claim, it may include in its decision a statement to that effect with its

reasons for so holding, which statement shall constitute a rejection of the claims.

Footnote 3.

3

Table set at this point is not available. See table in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

Footnote 4.

4

Table set at this point is not available. See table in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

Footnote 5.

5

Table set at this point is not available. See table in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

Footnote 6. Often during the prosecution of this application in the PTO and, indeed, in the arguments presented to this court, the term "synergism" is applied without qualification. Synergism, in and of itself, is not conclusive of unobviousness in that synergism might be expected. In re Huellmantel, 51 CCPA 845, 324 F.2d 998, 139 USPQ 496 (1963). A consideration of the board's decision as well as the appellants' and solicitor's arguments leads us to the conclusion that the correct statutory standard, i.e., nonobviousness, has been in contest throughout, even though the nomenclature has been imprecise.

Footnote 7. As an aside, it seems that appellants have foregone an excellent chance to educate both the PTO and the court in their science. The record is not clear as regards the industrial standards and practices in evaluating data such as those presented in the specification. Although industrial standards are not necessarily determinative of what constitutes an unobvious result, they should go a long way in evincing what one having ordinary skill in the art looks at in making a choice between compositions. See In re Luvisi, 52 CCPA 1063, 342 F.2d 102, 144 USPQ 646 (1965).

Footnote 8. The board also questioned the statistical significance of the proof. Admittedly, the number of plants used in the tests is not disclosed. Nevertheless, we see no reason to question the data on this basis without some indication either from the data or from the prior art that these types of tests give unreliable results.

- End of Case -

04年01月08日(木) 20時21分 宛先: OBLON

発信: FUJISAWA PAT/TM

R: 856

P. 05



EPA/EPO/OEB
D-80298 München
+49 89 2399-0
TX 523 656 epmu d
FAX +49 89 2399-4485

Eur pälsches
Patentamt

Generaldirektion 2

European
Patent Office

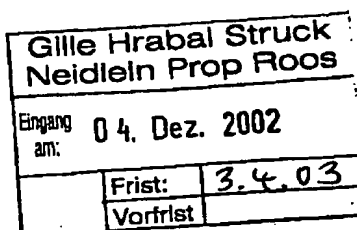
Directorate General 2

ATTACHMENT C

Office ur péen
des br vets

Direction Générale 2

Gille Hrabal Struck Neidlein Prop Roos
Patentanwälte,
Brucknerstrasse 20
40593 Düsseldorf
ALLEMAGNE



Telephone Numbers:

Primary Examiner +49 89 2399-8292
(substantive examination)

Formalities Officer / Assistant +49 89 2399-7271
(Formalities and other matters)



Application No. 99 959 751.1-2117	Ref. T 61 069-ok	Date 03.12.2002
Applicant FUJISAWA PHARMACEUTICAL CO., LTD.		

Communication pursuant to Article 96(2) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(1) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 78(2) and 83(2) and (4) EPC.

One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (Rule 36(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Article 96(3) EPC).



GOSSI
Primary Examiner
for the Examining Division

Enclosure(s): 2 page/s reasons (Form 2906)

04年01月08日(木) 20時21分 宛先: OBLON

発信: FUJISAWA PAT/TM

R: 856

P. 06

**Bescheld/Protokoll (Anlage)**

Datum
Date
Date 03.12.2002

Communication/Minutes (Annex)

Blatt
Sheet
Feuille 1

Notification/Procès-verbal (Annexe)

Anmelde-Nr.:
Application No.: 99 959 751.1
Demande n°:

The examination is being carried out on the following application documents:

Text for the Contracting States:

AT BE CH LI CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE

Description, pages:

1-231 as originally filed

Claims, No.:

1-10 as originally filed

1. The following documents (D) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: WO 98 57954 A (NAKAI KAZUO ; TAKE KAZUHIKO (JP); AZAMI HIDENORI (JP); EIKYU YOSHIT) 23 December 1998 (1998-12-23)
 D2: WO 97 22597 A (FUJISAWA PHARMACEUTICAL CO ; MATSUO MASAOKI (JP); MANABE TAKASHI (J) 26 June 1997 (1997-06-26)
 D3: WO 97 08166 A (SCHERING CORP) 6 March 1997 (1997-03-06)
 D4: EP-A-0 655 442 (FUJISAWA PHARMACEUTICAL CO) 31 May 1995 (1995-05-31)

2. An international preliminary examination report has already been drawn up for the present application in accordance with the PCT. The deficiencies mentioned in that report give rise to objections under the corresponding provisions of the EPC. In this respect following has chanced. The objection raised to the term "aryl" is within the inventive step analysis (under Art.56 EPC) based on the reason already given during the PCT phase.

The applicant is further reminded that

- a) in order to demonstrate an inventive step the patent application has to solve a technical problem and thereby make a technical contribution to the art (this is even more determinative in a case of a selection invention). The problem to be solved should be solved by the whole scope of the claimed subject-matter and not

04年01月08日(木) 20時21分 宛先: OBLON

発信: FUJISAWA PAT/TM

R: 856

P. 07

**Bescheld/Protokoll (Anlage)**Datum
Date
Date
03.12.2002**Communication/Minutes (Annex)**Blatt
Sheet
Feuille
2**Notification/Procès-verbal (Annexe)**Anmelde-Nr.:
Application No.:
Demande n°:
99 959 751.1

just by individual compounds tested (at present no data are available). If this were not the case an invention could arbitrarily be broadened to any limit without consideration whether the compounds are actually solving the problem underlying the invention.

- b) In this respect applicant's attention is drawn to Decision T939/92 (copy alleged) dealing with the issue as to whether or not the breadth of a claim has a proper support in the application as filed. According to this decision the question was whether or not a specific technical effect can be reasonably ascribed to the whole spectrum of chemical structures, or only to a part of it even regardless the structural similarity that the claimed compound may or may not have with any known chemical compound (point 4.1 of the Decision).
3. Any amendments carried out in response to this communication should strictly comply with Art.123(2) EPC and the description should be amended in accordance with any new set of claims filed. Any amendments should be typed (Rule 35 EPC).